| Notice of Allowability                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                     | Application No.            | Applicant(s)                           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------------|----------------------------------------|
|                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                            | 10/630,258                 | TAVERAS ET AL.                         |
|                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                            | Examiner                   | Art Unit                               |
|                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                            | Andrew B. Freistein        | 1626                                   |
|                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                            |                            |                                        |
| The MAILING DATE of this communication appears on the cover sheet with the correspondence address All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS. This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308. |                            |                                        |
| 1. This communication is responsive to <u>IDS filed 3/24/06</u> .                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                          |                            |                                        |
| 2. X The allowed claim(s) is/are 1, 4-14, 30-58, 62, 66, 67, 72, 77, 82-85, 88-91, 97-103 and 158-178 (now 1-82).                                                                                                                                                                                                                                                                                                                                                                                                                                                          |                            |                                        |
| <ul> <li>3. ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).</li> <li>a) ☐ All b) ☐ Some* c) ☐ None of the:</li> <li>1. ☐ Certified copies of the priority documents have been received.</li> </ul>                                                                                                                                                                                                                                                                                                                           |                            |                                        |
| 2. Certified copies of the priority documents have been received in Application No                                                                                                                                                                                                                                                                                                                                                                                                                                                                                         |                            |                                        |
| 3. Copies of the certified copies of the priority documents have been received in this national stage application from the                                                                                                                                                                                                                                                                                                                                                                                                                                                 |                            |                                        |
| International Bureau (PCT Rule 17.2(a)).                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                   |                            |                                        |
| * Certified copies not received:                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                           |                            |                                        |
| Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application. THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.                                                                                                                                                                                                                                                                                                                  |                            |                                        |
| 4. A SUBSTITUTE OATH OR DECLARATION must be submitted. Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL PATENT APPLICATION (PTO-152) which gives reason(s) why the oath or declaration is deficient.                                                                                                                                                                                                                                                                                                                                                           |                            |                                        |
| 5. CORRECTED DRAWINGS (as "replacement sheets") must be submitted.                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                         |                            |                                        |
| (a) 🔲 including changes required by the Notice of Draftsperson's Patent Drawing Review ( PTO-948) attached                                                                                                                                                                                                                                                                                                                                                                                                                                                                 |                            |                                        |
| 1) hereto or 2) to Paper No./Mail Date                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                     |                            |                                        |
| (b) ☐ including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No./Mail Date                                                                                                                                                                                                                                                                                                                                                                                                                                             |                            |                                        |
| Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet. Replacement sheet(s) should be labeled as such in the header according to 37 CFR 1.121(d).                                                                                                                                                                                                                                                                                                                            |                            |                                        |
| 6. DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.                                                                                                                                                                                                                                                                                                                                                                            |                            |                                        |
|                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                            |                            |                                        |
| Attachment(s)                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                              | 5. Motion of Informal D    | otant Application (PTO 152)            |
| <ol> <li>Notice of References Cited (PTO-892)</li> <li>Notice of Draftperson's Patent Drawing Review (PTO-948)</li> </ol>                                                                                                                                                                                                                                                                                                                                                                                                                                                  | 6. ⊠ Interview Summary     | atent Application (PTO-152) (PTO-413). |
|                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                            | Paper No./Mail Dat         | e <u>04132006</u> .                    |
| <ol> <li>Information Disclosure Statements (PTO-1449 or PTO/SB/0<br/>Paper No./Mail Date 2/23/06 &amp; 3/24/06</li></ol>                                                                                                                                                                                                                                                                                                                                                                                                                                                   | 8), 7. 🛭 Examiner's Amendr | nenvComment                            |
| 4.   Examiner's Comment Regarding Requirement for Deposit                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                  | 8. 🛛 Examiner's Stateme    | nt of Reasons for Allowance            |
| of Biological Material                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                     | 9.  Other                  |                                        |
|                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                            |                            |                                        |
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#### **DETAILED ACTION**

The amendment filed 2/23/2006 has been entered. Claims 1, 4-14, 30-58, 62, 66, 67, 72, 77, 82-85, 88-91, 97-124, 138 and 140-178 are currently pending. Claims 2, 3, 15-29, 59-61, 63-65, 68-71, 73-76, 78-81, 86, 87, 93-96, 125-137 and 139 were cancelled. There is no claim number 92.

#### Information Disclosure Statement

Applicant's information disclosure statements (IDS), filed on 4/12/2004, 2/23/2006 and 3/24/2006, have been considered. Please refer to Applicant's copies of the 1449 submitted herewith.

## Restriction Requirement

The restriction requirement is <u>withdrawn</u>. However, Applicant reserves the right to file divisional applications on non-elected subject matter.

# Claim Rejections - 35 USC § 112

Claims 1 and 96-99 were rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. As a result of the amendment filed 2/23/2006, the rejections are withdrawn.

#### Double Patenting

Claims 1-4, 6, 7, 9, 10, 15-18, 22-27 and 37-57 were provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over Claims 58, 59, 60, and 62 of Copending U.S. Pat. Application No.

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10/390,078. As a result of the claim amendment filed 2/23/2006, the provisional rejection is withdrawn.

# Examiner's Amendment

An examiner's amendment to the record appears below. Should the changes and/or additions be unacceptable to applicant, an amendment may be filed as provided by 37 CFR 1.312. To ensure consideration of such an amendment, it MUST be submitted no later than the payment of the issue fee.

Authorization for this examiner's amendment was given during a telephone interview with Attorney Henry Jeanette on April 12, 2006.

This application has been amended as follows:

1. Cancel claims 104-124, 138 and 140-157.

2. In claim 1, on page "-3-", at the end of line 4, after "(6) : ", and before "wherein said A group is substituted with", delete the semicolon ";".

#### Reasons For Allowance

The instant invention is a compound of the formula (IA), 
$$H$$
, the

pharmaceutically acceptable salts and solvates thereof and a pharmaceutical composition comprising an effective amount of a compound of claim 1 and a pharmaceutically acceptable carrier.

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The closest relevant art is Hu et al., WO 05/075447, which discloses the

WO 05/075447 was disclosed four years after the priority date of the present invention and is not considered prior art.

### Telephone Inquiry

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Andrew B. Freistein whose telephone number is (571) 272-8515. The examiner can normally be reached Monday-Friday, 8:30 am - 5:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Joseph M<sup>c</sup>Kane can be reached on (571) 272-0699. The fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at (866) 217-9197 (toll-free).

Andrew B. Freistein ´
Patent Examiner, AU 1626

seph K. McKane

Supervisory Patent Examiner, AU 1626